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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 08/819,669 | 03/17/1997 | THIERRY BOON | LUD-5253.5-D | 1995 |

24972 7590 12/06/2006

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| EXAMINER | |
|---|---|
| GAMBEL, PHILLIP | |
| ART UNIT | PAPER NUMBER |
| 1644 | |

DATE MAILED: 12/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 08/819,669 | BOON ET AL. | |
| | Examiner | Art Unit | |
| | Phillip Gambel | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *6/7/06; 8/14/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *183-191* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *183-191* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

1. Applicant's Status Inquiry, filed 8/14/06, has been acknowledged.

The Decision on Appeal Under 35 USC 134 by the Board of Appeals and Interferences (BPAI), mailed 6/7/06, has been mailed.

2. Upon reconsideration, the following New Grounds of Rejection have been set forth in this Office Action.

The examiner apologizes for any inconvenience to applicant in this matter.

3. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); In re Van Ornam, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and In re Goodman, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 183-191 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of commonly assigned U.S. Patent No. 5,843,448) (see 892, mailed 3/28/01).

Although the claims are not exactly the same, the patented claims drawn to MAGE-1 tumor rejection antigen precursor proteins and immunogenic compositions thereof anticipate the instant MAGE tumor rejection antigen precursor proteins and compositions thereof.

It has been well known for decades by the ordinary artisan that vaccines and immunogenic compositions often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

Further, it is noted that SEQ ID NO: 8 of the instant USSN 08/819,669 is the same sequence as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (e.g., see Example 5 on columns 7-8 of U.S. Patent No. 5,843,448).

Therefore, the instant claims anticipate or render obvious one another.
5. Claims 183-191 are directed to an invention not patentably distinct from claims 1-9 of commonly assigned U.S. Patent No. 5,843,448 for the reasons above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No. 5,843,448, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

It is noted that there is no inventor in common between the instant USSN 08/819,669 and U.S. Patent NO. 5,843,448.

Also, as noted in MPEP 804,03, applicant is reminded that:

> Applications or patents are "commonly owned" pursuant to 35 U.S.C. **103**(c)(1) if they were wholly or entirely owned by the same person(s), or organization(s)/business entity(ies), at the time the claimed invention was made. See MPEP § **706.02(l)(2)** for a detailed definition of common ownership.< Two inventions of different inventive entities come within the >common ownership< provisions of **35 U.S.C. 103(c)**>(1)< when:
>
> (A) the later invention is not anticipated by the earlier invention under **35 U.S.C. 102**;
>
> (B) the earlier invention qualifies as prior art for purposes of obviousness under **35 U.S.C. 103** against the later invention only under *>subsections< (f) or (g) of **35 U.S.C. 102**, or >under< 35 U.S.C. 102(e) for applications >pending on or after December 10, 2004, for reexamination proceedings in which the patent under reexamination was granted on or after December 10, 2004, and for reexamination proceedings in which the patent under reexamination was< filed on or after November 29, 1999; and

(C) the inventions were, at the time the later invention was made, owned by the same person or subject to an obligation of assignment to the same person

Here, applicant is reminded that common ownership means wholly or entirely owned by the same at the time the invention was made and that the patented claims anticipate the instant claims.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(f) he did not himself invent the subject matter sought to be patented.

7. Claims 183-191 are rejected under 35 U.S.C. § 102(f) because the applicants did not invent the claimed subject matter.

It is noted that SEQ ID NO: 8 of the instant USSN 08/819,669 is the same sequence as SEQ ID NO: 1 disclosed in Example 5 of U.S. Patent No. 5,843,448 (see 892, mailed 3/28/01) (e.g., see Example 5 on columns 7-8 of U.S. Patent No. 5,843,448).

The patented claims of U.S. Patent No. 5,843,448 are drawn to MAGE-1 tumor rejection antigen precursor proteins and immunogenic compositions, which anticipate the instant MAGE tumor rejection antigen precursor proteins and compositions thereof. Further, it has been well known for decades by the ordinary artisan that vaccines and immunogenic compositions often comprise an adjuvant to increase the immunogenicity of the immunogenic or vaccine composition of interest.

U.S. patents are presumed valid by U.S. courts unless proven otherwise. See 35 U.S.C. 282.

Given the presumption of validity of U.S. Patent No. 5,843,448 and that no inventors are in common between the instant USSN 08/819,669 and U.S. Patent No. 5,843,448,

there is ambiguity as to who invented the claims drawn to MAGE-1 and the MAGE tumor rejection antigen precursor proteins.

Because of this ambiguity, it is incumbent on applicants to provide a satisfactory showing, which would lead to a reasonable conclusion that the instant listed inventorship are the sole inventors of the claimed invention.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

The fax number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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December 4, 2006

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